



## EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A  
(Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions,  
Article 22(3))

**No. G24 011858 0072 Rev. 01**

**Certificate Holder: PAUL HARTMANN AG**

Paul-Hartmann-Str. 12  
89522 Heidenheim  
GERMANY

SRN Sys./Proc. Pack - DE-PR-000019925

The Certification Body of TÜV SÜD Product Service GmbH certifies that the Certificate Holder has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G24 011858 0072 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G24 011858 0072 Rev. 01)

<b>Report No.:</b>	713298912
<b>Preceding Certificate No.:</b>	G24 011858 0072 Rev. 00
<b>Valid from:</b>	2023-08-18
<b>Valid until:</b>	2028-01-02
<b>Date of Initial Issuance:</b>	2023-01-03

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-08-18





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**No. G24 011858 0072 Rev. 01**

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003142KA  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003143KC  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003144KE  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003145KG  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003146KJ  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003147KL  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003148KN  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures





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<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003150K9
<b>Intended Purpose:</b>	A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003151KB
<b>Intended Purpose:</b>	A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003152KD
<b>Intended Purpose:</b>	A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003153KF
<b>Intended Purpose:</b>	A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003154KH
<b>Intended Purpose:</b>	A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003302K8
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003303KA
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care





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<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003304KC
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003305KE
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003306KG
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003307KJ
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003308KL
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003310K7
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Basic UDI-DI:</b>	40495003311K9
<b>Intended Purpose:</b>	A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care





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**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003312KB  
**Intended Purpose:** A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003141K1  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization  
**Basic UDI-DI:** 40495003149KQ  
**Intended Purpose:** A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures

**The validity of this certificate** -  
**depends on conditions and/or**  
**is limited to the following:**

### Revision History:

Rev.	Dated	Report	Description
00	2023-01-03	713251619	-
01	2023-08-18	713298912	Supplemented: Change to the approved type(s)/device(s)